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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/709,162 | 11/10/2000 | Guillermo J. Tearney | 187718/US - 475387-00245 | 3219 |
| 30873 7590 01/06/2011 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177 | | | EXAMINER KISH, JAMES M | |
| | | | ART UNIT 3737 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/709,162 | Applicant(s) TEARNEY ET AL. | |
| | Examiner JAMES KISH | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-82, 84-102, 104-148 and 150-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-82, 84-102, 104-141, 147-148, 150-162 is/are rejected.
- 7) ☒ Claim(s) 142-146 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 28, 2010 have been fully considered but they are not persuasive.

On page 34, the Applicant argues that Kittrell fails to teach, suggest or disclose that **the image-forming lens arrangement forms an image of the anatomical structure**. Firstly, the lens arrangement that the Examiner described in the previous office Action both transmits light to the anatomical structure and then returns light which has interacted with the anatomical structure to a detector (*see* numeral **70** in Figure 23). The returning light which has interacted with the anatomical structure is essentially the image which is then received by the detector. Therefore, the lens arrangement of Kittrell does, in as much as the current application does, form an image. Secondly, unless there is a viewfinder to which the lens arrangement of the current application directs the light so that a physician directly views the anatomical structure (i.e., without the use of a CCD or ICCD and display means), then the lens arrangement does not form an image. The camera, as described on page 17, lines 7-19, forms the image.

At the last line on page 34 and the top of page 35, the Applicant states, "Thus, it appears that the Examiner equates this spectral analyzer 60 with the dispersive arrangement." The Examiner makes no such comparison between the spectral analyzer and the dispersive arrangement. As explicitly stated in the Advisory Action, "Lens 41 of Figure 21 forwards illumination light through an optical fiber to a dispersive

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arrangement (i.e., a prism), as illustrated in Figure 13D.” It is quite clear that the prism is the dispersive arrangement.

The Examiner notes that the independent claims of the current application provide for a system having a lens arrangement and a dispersive arrangement. Section 2114 of the MPEP states (with emphasis in the original), “‘Apparatus claims cover what a device *is*, not what a device *does*.’ *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).” Section 2114 of the MPEP states, “While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).” Therefore, the Applicant is essentially arguing that an apparatus comprising an image-forming lens arrangement configured to provide electromagnetic radiation there through and also having a dispersive arrangement (for example, a prism), is new and inventive. In other words, and broadly interpreted, a device having a lens and a prism. The first endoscope was invented in 1805 and the use of such devices became popular in the 1960's when optics were discovered. Furthermore, many other medical devices, for example, microscopes (and most likely, non-medical related devices) utilizing a lens and a prism have been created prior to the 1990's. Most importantly, Kittrell comprises a device having a least two lenses and a prism and the device is used to obtain information associated with an anatomical structure. Therefore, Kittrell covers what the device is, as well as covering what the

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device does (as has been previously explained in prior Office Actions and correspondences).

On the bottom of page 36, the Applicant argues that the Kittrell patent fails to provide teachings for the limitations of claim 147. The Examiner respectfully disagrees. Kittrell's device both illuminates the anatomical structure via the optical fiber as well as collects return light via the optical fiber. This returned light enters the optical fibers after passing through the lens/optical shield structure. Therefore, Kittrell teaches this limitation.

For at least the reasons as stated above, the rejection of the claims still stand and are repeated below.

Claim Objections

Claims 142-146 are objected to because of the following informalities:

On page 14 of the specification, the Applicant states that it is well known that a "minimum number of resolvable elements of about... 65,536 is needed to do meaningful diagnostic procedures." Furthermore, the discussion of resolvable points from pages 13-15 does not seem to explicitly state that a minimum of 100 resolvable points is used. The Table I on page 15 only goes as low as 625.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68-75, 81-82, 84-87, 89-95, 101-102, 104-107, 109-116, 118-128, 130, 137-140, 147-148, 152-157 and 161-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. (US Patent No. 5,318,024) – herein referred to as Kittrell. Kittrell discloses a laser endoscope for generating a spectrally resolved spatial (therefore, at *least* two-dimensional) image of tissue. Kittrell illustrates at least one lens arrangement in Figures 21 and 22 with numeral **40** and **41**, which guides light into optical fibers. Furthermore, Kittrell teaches that the shield **12** maybe use to control spot size by means of lenses inserted within the shield (column 5, lines 33-34). Also, Figure 23 illustrates a reflective mirror lens grating combination **68** at the return end of the device. In several embodiments of Kittrell, a lens, multiple lenses, holographic elements, gratings, prisms or a mirror can be used to control the location and divergence of laser light and return fluorescence or scattered light (column 13, lines 64-68). These elements (a lens, multiple lenses, holographic elements, gratings, prisms or a mirror) can be controlled by wires. Light from conventional sources may be used broadband, or it may be filtered or dispersed (column 20, lines 59-62). The laser catheter can be used to penetrate most types of tissues (column 6, lines 5-21), thereby modifying a property of the structure. As illustrated in Figure 25, the distal ends of the optical fibers are at different angles and column 8, lines 57-60 states that the distal ends

of the optical fibers are optically polished. As seen in Figure 17C, the light emitted from the end of the probe is made to overlap.

Regarding claim 147, Kittrell's device both illuminates the anatomical structure via the optical fiber as well as collects return light via the optical fiber. This returned light enters the optical fibers after passing through the lens/optical shield structure. Therefore, Kittrell teaches this limitation.

Regarding claim 148 of the current application, claim 1 of Kittrell states, "processing the separated light received by the detector with a computer such that the spectrally resolved light provides a displayable spatial image of the illuminated tissue."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 88, 108, 117, 129, 131-136, 141 and 158-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Olinger et al. (US Patent No. 3,941,121) – herein referred to as Olinger. Kittrell is discussed above in the rejection of claims 68, 89, 113, 125. However, Kittrell fails to provide a fluid displacement arrangement. Olinger teaches a needle endoscope including a hollow needle of about 18-gauge (*see Abstract*). To clear the area for better viewing in certain situations, a syringe can be connected to a luer lock, associated with the coupling, and warm normal saline solution can be injected through the electrode channel (column 10, lines 32-40). It would have been obvious to combine the teachings of Olinger with the device of Kittrell in order to provide operative visual supervision of a treatment procedure performed through an operative channel of the needle and which is small enough to be universally acceptable for introduction into previously inviolate tissue area without resorting to open surgery techniques (column 2, lines 56-62).

Claims 76-78 and 96-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Webb et al. (WO 99/44089) – herein referred to as Webb. Kittrell is discussed above in the rejection of claims 75 and 95. However, Kittrell fails to teach a specific number of resolvable points that make up the image. Webb teaches that the number of resolvable points is related to the total bandwidth of the

source and the bandwidth of the spectrum. The number of resolvable points may be any number governed by Equation (2) on page 3. An example is provided on page 4. Absent the showing of criticality, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create an image with any number of resolvable points based on the equation of Webb as a matter of design choice.

Claims 79-80 and 99-100 rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Baker et al. (US Patent No. 5,275,594) – herein referred to as Baker. Kittrell discloses a catheter used for diagnosis and removal of arterial or vascular obstructions (column 1, lines 14-16). See the previous description of Kittrell in the rejection of claims 68 and 89. However, Kittrell does not explicitly disclose a diameter for the probe. Baker teaches that the diameter of arteries is on the order of one to a few millimeters (column 1, lines 40-41). Therefore, it would be obvious to one of skill in the art at the time the invention was made to design the probe of Kittrell to have a diameter of less than about one millimeter in order to allow the device to enter any location in the arteries and vasculature of the patient, based on the teaching of Baker.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

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application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JMK